



AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings, of claims in the application:

1.-29. (Canceled).

30. (New) A pharmaceutical composition comprising a mixture of:

(a) an active macromolecular principle, and

(b) an aromatic alcohol absorption enhancer chosen from butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives thereof, wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principle.

31. (New) A pharmaceutical composition comprising a mixture of:

(a) an active macromolecular principle,

(b) an aromatic alcohol absorption enhancer chosen from propyl gallate, butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives thereof, wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principle, and

(c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media.

32. (New) A composition according to claim 30, wherein the mixture comprises less than 5% by weight of water.

33. (New) A composition according to claim 30, wherein the composition is coated with an enteric coating which becomes permeable at a pH of from 3 to 7.

34. (New) A composition according to claim 30, wherein the mixture comprises at least 1% by weight of the aromatic alcohol absorption enhancer.

35. (New) A composition according to claim 30, wherein the ratio by weight of the aromatic alcohol absorption enhancer to active macromolecular principle is at least 5:1.

36. (New) A composition according to claim 30, wherein the mixture is in the form of a solution or a microparticulate dispersion.

37. (New) A composition according to claim 30, wherein the mixture is in solid form.

38. (New) A composition according to claim 30, wherein the active macromolecular principle is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof.

39. A composition according to claim 30, wherein the aromatic alcohol absorption enhancer is chosen from BHT, BHA and analogues and derivatives thereof, including analogues and derivatives of hydroxy toluene or hydroxy anisole where the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group are replaced by linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl, either unsubstituted or substituted in any position, especially by halogen atoms.

40. A composition according to claim 31, wherein the aromatic alcohol absorption enhancer is propyl gallate or an analogue or a derivative thereof, including esters of gallic acid, where the esters may be linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl esters, and the compounds are optionally substituted with halogen, linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl esters.

41. (New) A composition according to claim 31, where the solubilization aid is chosen from a bile acid or salt, benzyl alcohol, phenyl ethanol, phenoxyethanol, transcitol and isopropanol.

42. (New) A composition according to claim 30, where the active macromolecular principle is insulin, calcitonin, growth hormone, parathyroid hormone, or erythropoietin, and derivatives and analogues, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

43. (New) A composition according to claim 30, where the active macromolecular principle is insulin, calcitonin, parathyroid hormone or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

44. (New) A composition according to claim 43, where the active macromolecular principle is insulin or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin and the composition further comprises an insulin sensitizing agent.

45. (New) A composition according to claim 30, for use in the therapeutic or diagnostic treatment of the human or animal body.

46. (New) A method of enhancing the absorption of an active macromolecular principle in a patient, which method comprises administering to said patient a composition as defined in claim 30.

47. (New) A method according to claim 46 wherein the composition enhances the absorption of a macromolecule across the intestinal wall.

48. (New) A method of enhancing the absorption of an active macromolecular principle in a patient, which method comprises administering to said patient an aromatic alcohol chosen from propyl gallate, butylated hydroxy toluene, butylated hydroxy anisole and analogues and

derivatives thereof together with a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media.

49. (New) A method according to claim 47, wherein the composition comprises less than 5% by weight of water.

50. (New) A method according to claim 48, wherein the solubilization aid is selected from a conjugated bile acid or salt, benzylalcohol, phenylethanol, phenoxyethanol, transcitol and isopropanol.

51. (New) A method according to claim 47, wherein the composition is comprised in a medicament, which medicament is provided in the form of a solution, as a microparticulate dispersion or as a solid.

52. (New) A method according to claim 47, wherein the macromolecule to be absorbed/active macromolecular principle is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof.

53. (New) A method according to claim 52, wherein the macromolecule to be absorbed/active macromolecular principle to be absorbed is selected from insulin, calcitonin, growth hormone, parathyroid hormone and erythropoietin, and derivatives and analogues thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

54. (New) A method according to claim 53, wherein the macromolecule to be absorbed/active macromolecular principle to be absorbed is insulin, calcitonin, parathyroid hormone or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin.

55. (New) A method according to claim 54, wherein the macromolecular principle is insulin or a derivative or an analogue thereof, either synthetic or from natural sources, conforming to structures derived from either human or animal origin, and an insulin sensitizing agent is also present.

56. (New) A method of treating a patient suffering from a condition or disease treatable by administration of a composition according to claim 30.

57. (New) A pharmaceutical composition comprising a mixture of:

- (a) an active macromolecular principle which is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof,
- (b) an aromatic alcohol absorption enhancer selected from butylated hydroxy toluene, butylated hydroxy anisole and analogues and derivatives thereof, including analogues and derivatives of hydroxy toluene or hydroxy anisole where the methyl group or the methoxy group linked to the aromatic ring and/or the hydrogen ortho to the hydroxyl group are replaced by linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl, either unsubstituted or substituted in any position, especially by halogen atoms, and wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principle, and
- (c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media, which is chosen from a bile acid or salt, benzyl alcohol, phenyl ethanol, phenoxyethanol, transcitol and isopropanol.

58. (New) A pharmaceutical composition comprising a mixture of:

- (a) an active macromolecular principle which is a polypeptide or protein, polynucleotide, polysaccharide or a mixture thereof,

- (b) aromatic alcohol absorption enhancer which is propyl gallate or an analogue or a derivative thereof, including esters of gallic acid, where the esters may be linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl esters, and the compounds are optionally substituted with halogen, linear or branched chain C_{1-12} alkyl, C_{1-12} alkyloxy, C_{1-12} alkylthio or C_{2-12} alkenyl esters, and wherein the aromatic alcohol absorption enhancer is present in an amount by weight greater than or equal to that of the active macromolecular principle, and
- (c) a solubilization aid capable of increasing the solubility of the aromatic alcohol absorption enhancer in aqueous media, which is selected from a bile acid or salt, benzyl alcohol, phenyl ethanol, phenoxyethanol, transcitol and isopropanol.